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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,111	09/15/2000	Charles J. Davidson	19601-000320US	3759

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/01/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,111

Applicant(s)

DAVIDSON ET AL.

Examiner

Paul B. Prebilio

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-19 and 42-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50-70 is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-19, 42-48 and 71 is/are rejected.
- 7) ☒ Claim(s) 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 31.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 20, 2003 has been entered.

Information Disclosure Statement

The information disclosure statement filed with a CD-ROM was considered. However, it was difficult and time consuming to consider the 124 references due to the format of the images. Therefore, the Examiner would like to make Applicant aware of electronic information disclosure statements (i.e. eIDS) as a more practicable means of providing prior art.

Priority

The new declaration has been accepted and entered into the file. Upon review of the priority documents, the Examiner concluded that the effective filing date of all the present claims is July 11, 2000.

The 35 USC 112, first and second paragraph rejections of the previous Office action have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, 10, 13, 16-19, 42, 44-48, and 71 are rejected under 35

U.S.C. 102(b) as being anticipated by Fischell et al (US 5,749,825). Fischell anticipates the claim language where the catheter as claimed is met by shaft (25) of Fischell (see Figure 1), the side member as claimed is met by side branch tube (24) of Fischell, the stent as claimed is met by stent (20) of Fischell. It is noted that the side member must be fixed to the shaft (25) at at least the crotch point to work and operate as shown; see Figure 3. This is due to the fact that the stent is not holding the side branch tube and the shaft to each other at the crotch point because pressure from the saddlepoint (4) biasing the branch tube and shaft apart must be counteracted upon by the crotch point attachment. Furthermore, the branch tube must be flexible and movable relative to the shaft; otherwise, it could not be advance through the main artery (1) with its separated diameter of Figure 1. The distal portion of the side member is "beneath" at least a portion of the stent because it is farther down the descending coronary artery; see column 5, lines 31-46. The side member of Fischell is movable with respect to the catheter because it is spread farther therefrom as it approaches the bifurcation.

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With regard to claim 13, since the side tube is made of metal, it is inherently fluoroscopically visible to some extent; see column 3, lines 15-18. Furthermore, the stent is fluoroscopically visible material.

With regard to claim 19, Applicant is directed to see column 3, lines 11-12.

Claims 1, 7, 10-12, 15-18, 42, and 45-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al (US 6,099,497). Adams anticipates the claim language where the catheter as claimed is element (20) and (28), the side member is catheter (30), the stent is element (80) with side hole (68); see Figures 6-9 and column 5, lines 13-59. The catheter (20) of Adams can be fixed to catheter (30) by sheath (22); see column 3, lines 13-30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (US 5,749,825) or Adams et al (US 6,099,497) in view of Fischell et al (US 5,669,932). Fischell ('825) or Adams meets the claim language but fails to mark both the side tube (24) and the shaft (25), but rather marks only the shaft at (30); see Figure 3. However, Fischell ('932) teaches that it was known to mark catheters in various locations in order to enable accurate positioning of stents; see especially the abstract. Hence, it would have been obvious to mark the Fischell ('825) side tube and shaft in a

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similar fashion in order to enable more accurate placement of the stents thereof; see Figure 5.

Claims 8, 11, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (US 5,749,825) in view of Richter et al (US 5,755,734). Fischell ('825) meets the claim language but fails to teach the use of the branch tube as a means to place side stent (40) in the branch artery as required by the present claims; see Figure 5 of Fischell. However, Richter teaches that it was known to use balloon catheters with guidewires in place side stents into proper position; see Figures 13-21. Hence, it is the Examiner's position that it would have been obvious to use the side branch tube (24) of Fischell as a means to place side stent (40) in place so it could be accurately and safely placed therein.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (US 5,749,825) or Adams et al (US 6,099,497) in view of Davila et al (US 5,851,464). Fischell ('825) or Adams meets the claim language except for the pebax and graphite catheter as claimed. However, Davila teaches that it was known to make catheters out of pebax and graphite; see column 3, lines 8-32. Hence, it is the Examiner's position that it would have been obvious to make the catheter of Fischell out of pebax and graphite for the same reasons that Davila does the same and in order to promote sliding between the catheter and guidewire.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (US 5,749,825) alone. Fischell discloses a stent (40) that portion that is distal to the location in the branches where part of the attachment is proximal to the stent but

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lacks the entire stent being distal of the fixed location as apparently required by the present claim language. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have an attachment location proximal of the stent (see Figure 1 where shaft joins the side tube and the balloon (23)) because Applicants have not disclosed that this modification results in some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the claims do not preclude attachments distally of the proximal end of the stent. Therefore, it would have been an obvious matter of design choice to modify Fischell to obtain the invention as specified in the claims.

Allowable Subject Matter

Claim 49 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 50-70 are allowed over the prior art of record.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

In response to the traversal of the Fischell rejection that the side member thereof is not beneath a portion of the stent, the Examiner modified the rejection to address this limitation. For this reason, Fischell is considered to read on the claimed invention.

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The traversal of the claims 49-70 rejections has been addressed in that the rejections have been withdrawn.

The Vardi et al (US 6,692,483) patent was cited, but found to not be prior art because it has the same inventive entity as the present application. In addition, the claimed subject matter therein, while close to the claimed subject matter of claims 49-70 of the present application (see claim 21 of the patent), is not considered to be obvious over the present claims under double patenting doctrine.


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.


Paul Prebilic
Primary Examiner
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